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VIA ELECTRONIC FILING

April 28, 2025

Honorable Michael A. Shipp, U.S.D.J.
United States District Court
Clarkson S. Fisher Building & US Courthouse
402 East State Street
Trenton, NJ 08608

Honorable Rukhsanah L. Singh, U.S.M.J.
United States District Court
Clarkson S. Fisher Building & US Courthouse
402 East State Street
Trenton, NJ 08608

**Re: J&J Defendants' Response to Plaintiffs' April 24, 2025
Correspondence (ECF No. 33755)
Case No.: 3:16-md-02738-MAS-RLS**

Dear Judge Shipp and Judge Singh:

The J&J Defendants respectfully submit this response to Plaintiffs' April 24, 2025 correspondence (ECF No. 33755) regarding the proposed rule issued on December 27, 2024, titled *Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products*, 89 Fed. Reg. 105490 (the "Proposed Rule").

First, the Proposed Rule is, of course, just that: a *Proposed* Rule. It is not a final rule and it is not binding as a matter of federal administrative law. It will not become a final rule until after FDA completes its formal rulemaking process, which includes sufficiently addressing the public comments received by the close of the comment period on March 27, 2025. Thus far, FDA has not done that. Therefore, there is no change in "current policy of the FDA" and the Proposed Rule is not relevant to this Court's adjudication of the issues before it. *See, e.g., Yocum v. United States*, 66 Fed. Cl. 579, 590 (Fed. Cl. 2005) ("[I]n general, proposed regulations have no legal force or effect until they become final."); *Tedori v. United States*, 211 F.3d 488, 492 (9th Cir. 2000) (citation omitted) (noting that "proposed regulations carry no more weight than a position advanced on brief"); *In re Murray*

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Energy Corp., 788 F.3d 330, 334 (D.C. Cir. 2015) (proposed rules do not “determine rights or obligations or impose legal consequences”). Indeed, in the most recent Johnson & Johnson trial, the court specifically excluded reference to the Proposed Rule for these very reasons. *See Doomey v. Johnson & Johnson et al.*, Case No. 21STCV47286, April 16, 2025 at 4718:25-4719:1 (“If you’re asking about the proposed rules by the FDA, ‘Isn’t it true that the proposed rules by the FDA . . .’ what does that mean? It means nothing to me. Okay. So under 352, I would exclude it.”), attached hereto as **Exhibit A**.

Second, if the Court does intend to consider the Proposed Rule, it should also consider the extensive record of comments critiquing it.

For example, the United States Pharmacopeia (“USP”) submitted comments questioning the need for the Proposed Rule given that USP had incorporated recent “revisions and improvements to the USP Talc monograph as well as the new General Chapters <901> and <1901> that may address some of the limitations and shortcomings mentioned in the Proposed Rule.” *See* USP’s March 27, 2025 Comments, attached hereto as **Exhibit B**. The USP has convened its USP Talc Expert Panels, comprised of experts from agencies including FDA, as well as experts from outside of the government, to perform an actual real-world study of various talc testing methodologies. *Id.* The purpose of the study was to establish empirically based recommendations for talc testing for more than a decade. *Id.* Based on that real-world study by testing experts, USP highlighted numerous disagreements with aspects of the Proposed Rule. USP noted that FDA provided no basis to support its assumption that transmission electron microscopy (“TEM”) will improve sensitivity above and beyond USP’s most recently revised USP Test for Asbestos that will become official this year. *Id.* USP also commented that the Proposed Rule’s method for determining whether a sample is positive “diverges from the current generally accepted TEM fiber counting procedures promulgated in certain United States laws and regulations, as well as in some international standard methods, including those used by the FDA’s referenced 200 samples...” *Id.*

These critiques from USP are not an isolated example. The rulemaking record is replete with examples of significant concerns raised regarding the Proposed Rule. *See, e.g.*, March 27, 2025 Comments from the National Association of Manufacturers, attached hereto as **Exhibit C**; March 27, 2025 Comments from the Consumer Healthcare Products Association, attached hereto as **Exhibit D**; March 27, 2025 Comments from the Essential Minerals Association, attached hereto as **Exhibit E**; March 27, 2025 Comments from Advanced Medical Technology Association, attached hereto as **Exhibit F**; March 27, 2025 Comments from Dr. Shu-Chun Su, attached hereto as **Exhibit G**; March 27, 2025 Comments from RJ Lee Group, attached hereto as **Exhibit H**; March 27, 2025 Comments from Segrave

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Technical Consulting, LLC, attached hereto as **Exhibit I**; and March 27, 2025 Comments from Benchmark Risk Group, attached hereto as **Exhibit J**. To the extent that this Court entertains Plaintiffs' request to supplement the record or take judicial notice of the Proposed Rule, J&J Defendants request that such record and judicial notice also include the materials attached hereto as **Exhibits B-J**.

Third, should the Court grant Plaintiffs' request concerning the Proposed Rule, J&J Defendants respectfully request the opportunity to introduce new peer reviewed scientific literature. This literature further advances the understanding that nonasbestiform minerals can be distinguished from asbestos and that such nonasbestiform minerals do *not* present the same health effects as asbestos. As one example, just this week Dr. Andrey Korchevskiy and Dr. Ann Wylie published a study in *Inhalation Toxicology* in which the authors developed an empirical metric called the "Dimensional Coefficient of Carcinogenicity (DCC)" to describe the mesotheliogenic potential of a population of particles based on Surface Areas and Widths. *The Empirical Metric of Mesothelial Carcinogenicity for Carbon Nanotubes and Elongate Mineral Particles*, Apr. 24, 2025, attached hereto as **Exhibit K**. They applied the DCC metric to a massive database of almost 250 different mineral populations involving more than 570,000 unique particles to confirm that DCC data correlated with mesothelioma potency of in human epidemiological studies and the mesothelioma rates in laboratory animal studies using these specific particle populations. They concluded that this empirical metric "demonstrates that non-asbestiform datasets (based on a widely representative database used in our study) are negligible by their potential mesothelial carcinogenicity." *Id.* at 16. This and other studies continue to advance the understanding that asbestos and nonasbestiform minerals do not present the same health effects. Therefore, methods such as those included in the Proposed Rule that fail to distinguish between these different types of particles have no scientific or public health basis, and recent scientific literature addressing these issues should also be presented to place the problems associated with the Proposed Rule in proper context.

Finally, on April 15, 2025 the Court issued an Order with a detailed agenda for an in-person status conference on June 17, 2025 in which a number of the motions that Plaintiffs seek to supplement are to be addressed. *See* ECF No. 33638. J&J Defendants understand that the Court wishes to limit the filing of motions and applications other than those that are routine. *Id.* As noted above, many scientific studies published during and after the Texas bankruptcy proceedings have continued to advance the understanding that asbestos and nonasbestiform minerals do not present the same health effects. Beyond this topic, there are many other significant developments that have come to light during this interval, including information

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directly undermining the epidemiology that Plaintiffs' experts rely upon, published critiques of the testing methodologies applied by Plaintiffs' experts in this matter, and criticisms of the processes employed by regulatory bodies including IARC in evaluating issues related to talc. J&J Defendants believe that the Court should be apprised of these recent developments as it considers pending dispositive motions. However, J&J Defendants are honoring the Court's request to limit the filing of non-routine motions and will raise these issues at the upcoming status conference on June 17, 2025 as requested.

Respectfully submitted,



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cc: All Counsel of Record (via ECF)

Enclosures: Exhibits A-K